TCT-8

First results of the EXPLORE trial, a Global, Randomized, Prospective, Multicenter Trial Investigating the Impact of Recanalization of a Chronic Total Occlusion on Left Ventricular Function in Patients after Primary Percutaneous Coronary Intervention for Acute ST-Elevation Myocardial Infarction

Jose P. Henriques,[1] Loes Hoebers,[2] Truls Råmunddal,[3] Peep Laanmets,[4] Erlend Eriksen,[5] Matthijs Bax,[6] Dan Ioanes,[7] Maarten J. Suttorp,[8] Bradley Strauss,[9] Emanuele Barbato,[10] Robin Nijveldt,[11] Albert C. van Rossum,[11] Koen Marques,[12] Jan G. Tijssen,[1] Rene J. van der Schaaf[13]
[1]Academic Medical Center - University of Amsterdam, Amsterdam, Netherlands; [2]Academic Medical Center, Amsterdam, Netherlands; [3]Sahlgrenska University hospital, Gothenburg, Sweden; [4]North-Estonia Regional Hospital, Tallinn, Estonia; [5]Haukeland University hospital, Bergen, AK; [6]Haga teaching Hospital, The Hague, Netherlands; [7]Sahlgrenska University Hospital, Gothenburg, Sweden; [8]Sint Antonius Hospital, Nieuwegein, Netherlands; [9]University of Toronto, Toronto, Canada; [10]Cardiovascular Center Aalst, Aalst, Belgium; [11]VU University Medical Center, Amsterdam, Netherlands; [12]VU University Medical Center, Amsterdam, Netherlands; [13]OLVG, Amsterdam, Netherlands

BACKGROUND In the setting of primary percutaneous coronary intervention (PPCI), patients with a concurrent chronic total occlusion (CTO) in a non-infarct related artery (IRA) were recently identified as a high-risk subgroup. It is unclear whether ST-elevation myocardial infarction (STEMI) patients with a CTO in a non-IRA should undergo additional percutaneous coronary intervention of the chronic total occlusion on top of optimal medical therapy shortly after PPCI. Possible beneficial effects include reduction in adverse left ventricular remodeling and preservation of global left ventricular function and improved long term clinical outcome.

METHODS The EXPLORE trial is a global randomized, prospective, multicenter, two-arm trial with blinded evaluation of endpoints. A total of 304 patients were included after successful PPCI for STEMI with a concurrent CTO in a non-IRA and were randomized to either elective PCI of the CTO within 7 days or standard medical treatment. Primary endpoints are left ventricular ejection fraction and left ventricular end-diastolic volume assessed by cardiac Magnetic Resonance Imaging at four months, analyzed by an independent corelab. All events underwent independent monitoring and were adjudicated by an independent critical events committee. Furthermore, all angiographies were reviewed by an independent corelab.

RESULTS In total, 304 STEMI patients with a CTO were included from 07-11-2007 until 30-03-2015. Data is currently analyzed.

CONCLUSIONS The ongoing EXPLORE trial is the first randomized clinical trial powered to investigate whether recanalization of a chronic total occlusion in a non-infarct related artery after primary percutaneous coronary intervention for ST-elevation myocardial infarction results in a better preserved residual left ventricular ejection fraction, reduced end-diastolic volume and enhanced clinical outcome.

CATEGORIES CORONARY: Acute Myocardial Infarction

KEYWORDS Acute myocardial infarction, Chronic total occlusion, Left ventricular function

TCT-9

Early PICSO preserves LVEF in porcine acute myocardial infarction

Roger Kessels,[1] Amelie Bouchard,[2] Louis-Georges Guy,[3] Guy LeClerc,[4] H. Ibrahim Korkmaz,[5] Hans W. Niessen,[6] Gregg W. Stone[7]
[1]Miracor Medical GmbH, Vienna, Austria; [2]AccelLAB, Broisbriand, Quebec, Canada; [3]AccelLAB, Boisbriand, Quebec, Canada; [4]AccelLAB, Boisbriand, Quebec, Canada; [5]VU medical center, Amsterdam, Netherlands; [6]VU Medical Center, Amsterdam, Netherlands; [7]Columbia University Medical Center and the Cardiovascular Research Foundation, New York, NY

BACKGROUND A major determinant of mortality and morbidity is the extent of myocardial necrosis after STEMI, and strategies to limit infarct size may therefore improve prognosis. As recently demonstrated in human studies, pressure-controlled intermittent coronary sinus occlusion (PICSO) may enhance myocardial recovery in acute myocardial infarction. Whether coronary sinus occlusion should be established before reperfusion is unknown.

METHODS In a prospective, controlled study, 28 pigs undergoing 90 minutes of left anterior descending (LAD) coronary artery balloon occlusion followed by reperfusion were randomly assigned to 3 groups: Early PICSO (starting 10 minutes prior to reperfusion, group A, n=9), Late PICSO (starting 30 minutes post reperfusion, group B, n=10), or reperfusion only (group C, n=9). PICSO was administered in an automatic mode for 90 minutes after initiation. Mean PICSO quantity was defined as the sum of the coronary sinus pressure modulation for all PICSO cycles. Infarct size (% left ventricular mass), microvascular obstruction (MVO), and left ventricular function were assessed by cardiac magnetic resonance imaging (MRI) on day 5. VEGF receptor expression was assessed by immunohistochemistry after sacrifice on day 5.

RESULTS The histologic and MRI group mean values for percent infarct size were numerically lowest in Group A when compared to Group B and Group C, albeit not reaching significance (13.5%±5.8% vs. 16.6%±3.6% vs. 16.2%±4.2% respectively, p=0.31). The same was true for MVO (3.2%±3.5% vs. 6.4%±7.7% vs. 8.8%±7.1% respectively, p=0.16). However, left ventricular ejection fraction (LVEF) was greatest in the Early PICSO group (61.0±7.0% vs. 50.2±9.8% vs. 52.3±7.3% respectively, p=0.02), as was wall thickening (49.7±15.0 vs. 33.7±15.1 vs. 39.5±7.0 respectively, p=0.045). Compared to control, group A animals had 3-fold greater expression of VEGF-R1 in the myocardial zone remote from the infarct (median [IQR] 19 [12-24] vs. 9 [6.8-11.5] vs. 5 [3.5-8] respectively, p=0.001). Group B animals had 2-fold greater expression of VEGF-R2 in the border zone of the infarct compared to control (5 [3.5-9], 14.5 [9.5-16], 6 [5-12.5], respectively). No safety issues were noted.

CONCLUSIONS PICSO was safely applied in a porcine model of LAD infarction. MRI at day 5 showed greater LVEF, better wall thickening, and trends toward smaller infarct size and MVO in animals treated with early PICSO, suggesting a cardioprotective effect of PICSO. In addition, PICSO resulted in an increased VEGF-R1 expression in the remote zone and VEGF-R2 in the border zone indicating, increased neo-angiogenic activity. Large trials are underway to demonstrate the benefits of PICSO in humans.

CATEGORIES CORONARY: Acute Myocardial Infarction

KEYWORDS Cardioprotection, Microvascular injury, ST-segment elevation myocardial infarction

BIORESORBABLE VASCULAR SCAFFOLDS

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TCT-10

Clinical outcomes following "full-plastic jacket" bioresorbable scaffold implantation

Hiroyoshi Kawamoto,[1] Azeem Latib,[1] Neil Ruparelia,[1] Akihito Tanaka,[1] Alessandro Sticchi,[2] Francesco Giannini,[2] Alaide Chieffo,[2] Mauro Carlino,[2] Matteo Montorfano,[2] Antonio Colombo[1]
[1]EMO GVM Centro Cuore Columbus/San Raffaele Scientific Institute, Milan, Italy; [2]San Raffaele Scientific Institute, Milan, Italy

BACKGROUND When performing percutaneous coronary intervention (PCI) for long-diffuse lesions, the best revascularization strategy remains unclear with options including treating most of the vessel length as opposed to a focal approach. A common option is to create a "full-metal jacket (FMJ)". However, FMJ may preclude future surgical revascularization and may be associated with higher events rates at follow-up. The use of bioresorbable scaffolds (BRS) is therefore very attractive by virtue of their full reabsorption 2 to 3 years after implantation. We aimed to investigate the feasibility and updated clinical outcomes following BRS implantation for very long lesions ("full-plastic jacket").

METHODS We analyzed consecutive patients who underwent PCI with Absorb BRS (Abbott Vascular, Santa Clara, CA) between May 2012 and April 2015. Procedural "full-plastic jacket" (FPJ) was defined as a continuous implantation of BRS with 60mm length or more. During the study period, 290 lesions (196 patients) treated with BRS (total length < 60mm) and 35 lesions (35 patients) treated with FPJ were identified.

RESULTS Patients treated with FPJ had a higher prevalence of diabetes (40.0% vs. 22.4%, p=0.03), chronic total occlusion (17.1% vs.